FDA 510(k) Premarket Notification

K013737 MODIFICATION TO: 3-LUMEN DURALON OCCLUSION BALLOON

CLEARED

Mar 1, 2002
108 days to decision

K013737 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k013737/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 13, 2001
Decision date	Mar 1, 2002
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Telemed Systems, Inc.**
Location	Hudson, MA, US
Contact	MICHAEL CARROLL
510(k) history	22 submissions · 22 cleared · 1990-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k013737/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026